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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,799	11/23/2001	George Jackowski	2132.086	5599

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EXAMINER	
CHERNYSHEV, OLGA N	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 11/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/991,799	JACKOWSKI ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 39-46* is/are pending in the application.

4a) Of the above claim(s) *39-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. Claim 1 has been amended, claims 2-38 have been cancelled and claims 39-46 have been added as requested in the amendment of Paper No. 14, filed on August 21, 2003. Claims 1 and 39-46 are pending in the instant application.

Newly submitted claims 39-46 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 39-43 are directed to methods of diagnosing Alzheimer's disease, classified in class 435, subclass 4, for examples; and claims 44-46 are directed to a diagnostic kit, classified in class 530, subclass 387.1, for example. Invention of claim 1 and the invention of claims 39-46 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the peptide of claim 1 could be used in an entirely different manner such as for the production of antibodies rather than in the methods of claims 39-43 or in the kit of claims 44-46.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 39-46 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim 1 is under examination in the instant office action.

2. Applicant's argument of the decision *In re Ochiai* (pages 10-11 of the Response) is noted but is not deemed persuasive, as PTO practice in view of that decision is directed to rejoinder of claims after allowable subject matter has been indicated, and not to withdrawal of restriction requirements. Applicant is advised that at such time as elected product claim(s) are indicated as being allowable, rejoinder of claims drawn to methods of using such may be requested under 35 U.S.C. § 103(b) pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86). Such rejoinder is *not* tantamount to a withdrawal of the restriction requirement.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed on August 21, 2003 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

6. Claim 1 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for those reasons of record in section 4 of Paper No. 11.

Applicant traverses the rejection on the premises that "mass spectrometric and chromatographic techniques are well-known to one of skill in the art, thus [...] one of skill in the art would know how to carry out the protocols in the instant disclosure" (page 15, last paragraph of the Response). The Examiner fully agrees with this statement. However, the issue at hand

which remains is not the ability of one to "carry out the protocol" but the ability of one to use the invention with a reasonable expectation of success. The Examiner maintains the position, which was fully explained in the previous office action, that the instant specification, as filed, fails to provide any evidence or sound scientific reasoning that would support a conclusion that the presence of an isolated peptide consisting of amino acid residues 2-18 of SQE ID NO: 1 would provide diagnosis of Alzheimer's disease.

Applicant argues that comparison of the lanes shown in Figure 1 between serum samples of Alzheimer's disease patients and normal control "provides evidence that the claimed biopolymer marker is specifically associated with Alzheimer's disease" (page 16, second paragraph of the Response). Applicant provides explanation of Figure 1, which in summary reflects that band 2, which correlates with the claimed biopolymer marker, is strongly present in four AD samples and is absent in four normal controls and one normal serum sample. However, analysis of the data provided in Figure 1 appears to be in conflict with Applicant's statement. Figure 1 is a photograph of a gel containing 10 standard lanes. Lanes 1-4 are AD samples, 5-8 are normal aged control, lane 9 is a pooled NHS (normal human serum) control and lane 10 is designated for molecular weight standards. Contrary to Applicant's statement that band 2 is present only in the first four AD samples, there appears to be no visible difference in intensity of band 2 in, for example samples 1 and 4 (which are AD samples) as compared to control samples of lanes 5-9. Therefore, because the instants specification does not provide precise protocol on how to analyze the data obtained by the disclosed protocol, one skilled in the art would clearly have to resort to substantial amount of undue experimentation in order to be able to use the instant claimed peptide 2-18 of SEQ ID NO: 1 as a marker for Alzheimer's disease.

The Declaration of Landers under 37 CFR 1.132 filed August 21, 2003 is insufficient to overcome the rejection of claim 1 for the following reasons. The Declaration provides additional data obtained by MS analysis regarding the absence of the claimed peptide in normal sera as compared to sera from patients with Alzheimer's disease (it is not explained if one sample of AD and one of control was analyzed or the results present again pooled serum samples). However, even if to assume that the claimed peptide could be used for diagnosis of Alzheimer's disease by mass spectrometry only, the series of questions regarding the description of the samples used for analysis remains unanswered. Applicant submits that the reference of Clark et al., which clearly states that a definitive diagnosis of Alzheimer's disease could be only made during postmortem examination or at brain biopsy, is ten years old and, therefore, does "not provide convincing evidence to describe state of the art at the time that the instant invention was made". This argument has been fully considered but is not deemed persuasive because, although ten years old, the reference of Clark et al. still represents the state of the art in the field of diagnosis of Alzheimer's disease. If Applicant is aware of any art, which was available prior to the filing date of the instant application, which describes any method of definitive diagnosis of Alzheimer's disease by methods other that direct brain tissue analysis, then Applicant is strongly encouraged to make such art of record. Moreover, the instant specification, as filed, fails to present any description of the samples used in experiments to determine the presence or absence of the claimed marker. There is also no information presented regarding presence or absence of the instant peptide 2-18 of SEQ ID NO: 1 in serum samples of pathological conditions other than Alzheimer's disease, or serum samples of patients suspected of having Alzheimer's disease, in which such marker would be present, followed up by a diagnosis of AD by using other

diagnostic methods. A skilled practitioner readily recognizes that in the absence of such critical information Applicant's invention is incomplete, and that it would require a substantial amount of undue experimentation to discover how to use the claimed biopolymer marker 2-18 of SEQ ID NO: 1 in diagnosis of Alzheimer's disease.

Conclusion

7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D. OC
November 24, 2003

JOHN ULM
PRIMARY EXAMINER
GROUP 1600